

### Subpart B—Active Ingredients

#### § 341.12 Antihistamine active ingredients.

The active ingredient of the product consists of any of the following when used within the dosage limits established for each ingredient:

- (a) Brompheniramine maleate.
- (b) Chlorcyclizine hydrochloride.
- (c) Chlorpheniramine maleate.
- (d) Dexbrompheniramine maleate.
- (e) Dexchlorpheniramine maleate.
- (f) Diphenhydramine citrate.
- (g) Diphenhydramine hydrochloride.
- (h) Doxylamine succinate.
- (i) Phenindamine tartrate.
- (j) Pheniramine maleate.
- (k) Pyrilamine maleate.
- (l) Thonzylamine hydrochloride.
- (m) Triprolidine hydrochloride.

[57 FR 58374, Dec. 9, 1992, as amended at 59 FR 4218, Jan. 28, 1994]

#### § 341.14 Antitussive active ingredients.

The active ingredients of the product consist of any of the following when used within the dosage limits and in the dosage forms established for each ingredient in § 341.74(d):

(a) *Oral antitussives*. (1) Chlophedianol hydrochloride.

(2) *Codeine ingredients*. The following ingredients may be used only in combination in accordance with §§ 329.20(a) and 341.40 and 21 CFR 1308.15(c).

- (i) Codeine.
- (ii) Codeine phosphate.
- (iii) Codeine sulfate.
- (3) Dextromethorphan.
- (4) Dextromethorphan hydrobromide.
- (5) Diphenhydramine citrate.
- (6) Diphenhydramine hydrochloride.
- (b) *Topical antitussives*.
- (1) Camphor.
- (2) Menthol.

[52 FR 30055, Aug. 12, 1987, as amended at 59 FR 29174, June 3, 1994]

#### § 341.16 Bronchodilator active ingredients.

The active ingredients of the product consist of any of the following when used within the dosage limits established for each ingredient:

- (a) Ephedrine.
- (b) Ephedrine hydrochloride.
- (c) Ephedrine sulfate.

- (d) Epinephrine.
- (e) Epinephrine bitartrate.
- (f) Racephedrine hydrochloride.
- (g) Racepinephrine hydrochloride.

[51 FR 35339, Oct. 2, 1986]

#### § 341.18 Expectorant active ingredient.

The active ingredient of the product is guaifenesin when used within the dosage limits established in § 341.78(d).

[54 FR 8509, Feb. 28, 1989]

#### § 341.20 Nasal decongestant active ingredients.

The active ingredient of the product consists of any of the following when used within the dosage limits and in the dosage forms established for each ingredient:

- (a) *Oral nasal decongestants*. (1) Phenylephrine hydrochloride.
- (2) Pseudoephedrine hydrochloride.
- (3) Pseudoephedrine sulfate.
- (b) *Topical nasal decongestants*. (1) [Reserved]
- (2) Ephedrine.
- (3) Ephedrine hydrochloride.
- (4) Ephedrine sulfate.
- (5) [Reserved]
- (6) Naphazoline hydrochloride.
- (7) Oxymetazoline hydrochloride.
- (8) Phenylephrine hydrochloride.
- (9) Propylhexedrine.
- (10) Xylometazoline hydrochloride.

[59 FR 43409, Aug. 23, 1994]

### Subpart C—Labeling

#### § 341.70 Labeling of OTC drug products containing ingredients that are used for treating concurrent symptoms (in either a single-ingredient or combination drug product).

The statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) *For products containing diphenhydramine citrate and diphenhydramine hydrochloride identified in § 341.14(a)(5) and (a)(6)*. The labeling of the product contains the established name of the drug, if any, and identifies the product as an “antihistamine/cough suppressant” or “antihistamine/